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| 09/875,660 | 06/05/2001 | Byron Lambert | ACS-58284 (1931P) | 7403 |

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EXAMINER

PHAM, HAI CHI

ART UNIT PAPER NUMBER

2861

DATE MAILED: 03/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/875,660

Applicant(s)

LAMBERT ET AL.

Examiner

Hai C Pham

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-- The MAILING DATE of this communication appears n the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 22-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 31-44 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 June 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7,9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-21 and 31-44, drawn to a method of determining a radiation dosage for sterilizing a medical product using a calorimeter, classified in class 422, subclass 22.
 - II. Claims 22-30, drawn to a method of calibrating a calorimeter used in a radiation process, classified in class 374, subclass 32.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are mutually exclusive. Invention I is directed to the measurement of a radiation dosage for sterilizing a medical product by using a calorimeter while invention II is directed to the routine calibration of the calorimeter, which would be used in any application.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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4. Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group I, e.g., "determining whether a calorimeter has received less than a maximum lifetime radiation dose" is pertinent to Group II but is not required for Group I, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Attorney Paul Y. Feng on March 12, 2003 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-21 and 31-44. Affirmation of this election must be made by applicant in replying to this Office action. Claims 22-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

8. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in **claim 40**. Therefore, the "**movable robotic**

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arm" must be shown or the feature canceled from claim 40. No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 5, 6, 11, 18, 31, 34-35, 39, 41-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Murray et al. (U.S. 3,790,794).

Murray et al., an acknowledged prior art, discloses a device and method for determining radiation dose by measuring a change of temperature in a material due to incident radiation on the material. The device includes a radiation source, which emits a radiation dose, a calorimeter, which is configured to be irradiated by the radiation source, and a calorimeter controller for determining the radiation dosage based on the difference between the temperature of the calorimeter before and after the irradiation of the calorimeter, the temperature difference being a function of the radiation dose received from the radiation source, and being used to calculate the receive radiation dose (col. 3, line 43 to col. 4, line 15).

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With regard to claims 11, 41, Murray et al. further teaches the provision of a calorimeter control system and a validated thermistor calorimeter having a validated resistance-temperature calibration relationship and a validated temperature-dosage calibration relationship (col. 4, lines 20-41).

With regard to claims 18 and 34-35, Murray et al. teaches the radiation source being a high-dose rate radiation source (14MeV electrons) providing a dose of electron beam.

Although Murray et al. does not explicitly disclose the device being used for sterilizing a medical product, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 2-4, 7-10, 14-15, 32-33, 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murray et al. in view of Douglas-Hamilton et al. (U.S. 4,812,663).

Murray et al. discloses all the basic limitations of the claimed invention except for the conveyor with a closed-loop route, and the controller being a computer-controlled automatic controller.

However, Douglas-Hamilton et al. discloses a calorimetric dose monitor provided with a conveyor (rotating support disc 11) carrying the thermistor calorimeter (10) pass the radiation station, the conveyor having a short and closed-loop route, which convey the thermistor calorimeter from a starting position to an ending position within a short time (col. 7, lines 35-60). Douglas-Hamilton et al. further teaches the measurement of the radiation dose being performed and automatically controlled by the computer (190).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to incorporate a short, closed-loop-route conveyor as taught by Douglas-Hamilton et al. in the device of Murray et al. By doing so, a repeated measurement of the radiation dose can be automatically made possible.

13. Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murray et al. in view of Bowen et al. (Appl Note #4, ILX Lightwave).

Murray et al. discloses all the basic limitations of the claimed invention except for the time period for measuring the temperature change.

However, Applicants' provision of the App Note #4 from Bowen et al., discloses the temperature of the thermistor calorimeter being efficiently monitored when the temperature is allowed to become stabilized after a period of time of about 15 minutes.

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It would have been obvious at the time the invention was made to a person having ordinary skill in the art to allow the temperature of the thermistor calorimeter of Murray et al. to stabilize before making the measurement as taught by Bowen et al.'s App Note #4. By doing so, the temperature measurement would be more accurate.

14. Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murray et al. in view of Douglas-Hamilton et al., as applied to claims 11, 14, 15 above, and further in view of Bowen et al. (Appl Note #4, ILX Lightwave).

Murray et al., as modified by Douglas-Hamilton et al., discloses all the basic limitations of the claimed invention except for the time period for measuring the temperature change.

However, Applicants' provision of the App Note #4 from Bowen et al., discloses the temperature of the thermistor calorimeter being efficiently monitored when the temperature is allowed to become stabilized after a period of time of about 15 minutes.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to allow the temperature of the thermistor calorimeter of the modified device of Murray et al. to stabilize before making the measurement as taught by Bowen et al.'s App Note #4. By doing so, the temperature measurement would be more accurate.

15. Claims 19-21, 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murray et al. in view of Ichihara (U.S. 6,030,554).

Murray et al. discloses all the basic limitations of the claimed invention except for the range of the radiation dose being monitored.

However, Ichihara discloses a method and apparatus for sterilizing intraocular lens by electron beam where the radiation dose (preferably 15-70 kGy), the frequency, and the time period of the energy treatment are suitably determined so as to obtain a desired effect (free of microorganisms) without deteriorating and/or discoloring the intraocular lens.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to provide the device of Murray et al. with a proper radiation dose as taught by Ichihara. By doing so, one would prevent the product under radiation from deterioration.

16. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Murray et al. in view of Yamaguchi et al. (JP 7-198513).

Murray et al. discloses all the basic limitations of the claimed invention except for the movable robotic arm.

However, Yamaguchi et al. discloses a distribution type force-sensing detection sensor, which includes a movable robotic arm (Fig. 1) capable of detecting resistances of a work, whose measurements are used to calculate the indicated force.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to provide a movable robotic arm capable of measuring

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resistances as taught by Yamaguchi et al. in the device of Murray et al. By doing so, the radiation dosage can be determined in an automatic and safe way.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hai C Pham whose telephone number is (703) 308-1281. The examiner can normally be reached on T-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Benjamin R. Fuller can be reached on (703) 308-0079. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7722, (703) 308-7724, (703) 308-7382, (703) 305-3431, (703) 305-3432 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.



**HAI PHAM
PRIMARY EXAMINER**

March 12, 2003